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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/782,266      | 02/18/2004  | Petrus A. Besselink  | PARGN.002C1C1       | 4210             |

20995 7590 09/23/2009  
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| EXAMINER |
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SONNETT, KATHLEEN C

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| ART UNIT | PAPER NUMBER |
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3731

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

09/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/782,266 | <b>Applicant(s)</b><br>BESSELINK, PETRUS A. |  |
|                              | <b>Examiner</b><br>KATHLEEN SONNETT  | <b>Art Unit</b><br>3731                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 91-95, 113-122, 127-141 and 143-154 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 113-118, 130-133, 135, 138, 139, 141, 145-149, 152 and 154 is/are allowed.
- 6) ☒ Claim(s) 91-95, 119-122, 127-129, 134, 136, 137, 140, 143, 144, 150, 151 and 153 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/17/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 150** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 150 includes that at least one cell passes a transition point that allows the radially outward force to be decreased. However, the radially outward force of claim 150 refers to the radial force applied against a surface of a passageway and it is unclear how this force is decreased after the stent reaches a configuration that allows it to continue expansion without further force applied to the stent. Continued expansion would appear to increase the radially outward force on the surface of the passageway. Additionally, it seems that the expandable device does not apply an outward force against the surface of the passageway until the device is fully expanded. In other words, it appears that the force of claim 150 is not referring to the same force of claim 91 from which it depends.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

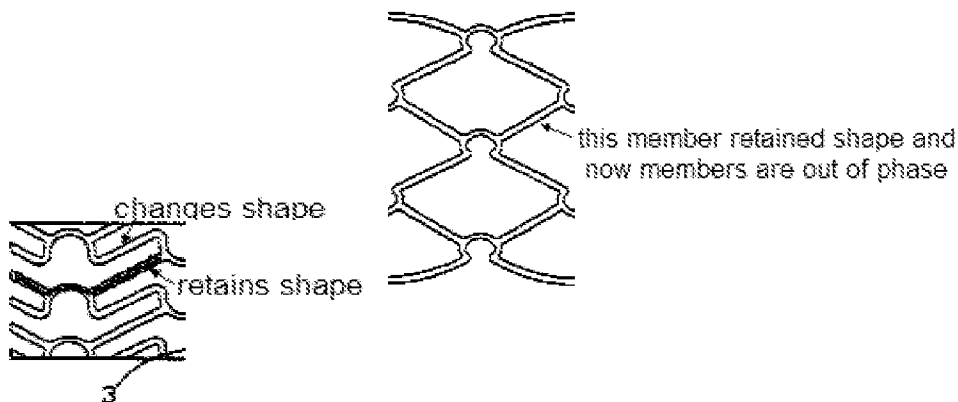
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. **Claims 91, 93, 94, and 134** are rejected under 35 U.S.C. 102(e) as being anticipated by Kanesaka et al. (US 5,776,183; "Kanesaka"). Kanesaka discloses a method of applying a radial force against a surface of a passageway with an expandable device comprising providing an expandable device with a plurality of cells comprising a generally longitudinal wave-like first member and a generally longitudinal wave-like second member, at least one cell capable of being expanded between a stable contracted state in which the first and second members are generally in phase (fig. 5) and at least one stable expanded state in which the first and second members are generally out of phase (fig. 6) and radially expanding the expandable device against a surface of the passageway (col. 4 ll. 32-47), such that the at least one cell is expanded from the stable contracted to stable expanded state wherein one of the first and second members substantially retains its shape when the cell transitions from the contracted to the expanded state (figs. 5 and 6). The figures below have been taken by the examiner from figs. 5 and 6 of Kanesaka. The wave-like member that retains its shape has been colored in by the examiner.

5. Regarding claim 94, the stent can be considered a liner as it lines a blood vessel.

6. Regarding claim 134, Kanesaka discloses placing the stent within a body of a patient.



**Claim Rejections - 35 USC § 103**

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 143** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka.

Kanesaka discloses the invention substantially as stated above but fails to expressly disclose that the cell is capable of being expanded between the stable contracted and stable expanded configurations without any stable configurations therebetween, since the stent is balloon-expandable. However, it is well known to construct stents such that they are self-expandable and it would have been within the purview of one skilled in the art to construct the stent of Kanesaka so that it is self-expanding, in order to gain the advantages associated with self-expansion, such as smaller stent profiles during delivery. It would have also been obvious to achieve this self-expansion by using a shape memory material. Cold saline solution can be delivered to keep the stent stable in its collapsed form while in the catheter. Once delivered, the stent is stable in its expanded form at body temperature.

9. **Claims 92, 95, and 151** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka in view of Gray (US 5,895,406). Kanesaka discloses the invention substantially as stated above but fails to expressly disclose that the stent does not substantially shorten when expanded or that the stent comprises thick struts coupled to thin struts.

10. Gray teaches that it is known to produce a stent that does not shorten during expansion (col. 3 ll. 26-27). Gray further teaches that it is known to increase the thickness of a stent at its ends in order to eliminate any flaring that might occur at the ends of the stent (col. 3 ll. 52-60). This results in a stent with thicker struts at the ends of the stent than in the middle. It would have been obvious to one skilled in the art to construct the stent of Kanesaka so that the stent does

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not substantially shorten during expansion and that has thicker struts at the ends in order to easily determined the expanded size of the stent based on its contracted size and to avoid flaring at the ends of the stent.

11. **Claims 119-122, 127-129, 136, 137, 144, and 153** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray. Gray discloses a method comprising an expandable device with a plurality of bistable cells, each of the bistable cells comprising first and second arcuate members, each cell capable of assuming a stable collapsed configuration in which the first and second arcuate members are in phase and a stable expanded configuration in which the arcuate members are out of phase, the expandable device having a generally tubular shape. It is noted that bistable can include more than 2 stable positions as indicated in the instant application (page 19, ll. 22-23). The device of Gray is balloon expandable (col. 4, ll. 39-40), and therefore it will be stable in both the collapsed and expanded configuration and is capable of isothermally expanding to this stable expanded configuration. Gray does not expressly disclose surrounding the expandable device with an expandable liner element attached to an outer surface of the device. However, expandable, deformable, and elastomeric material grafts, sleeves, or coating applied to stents are well known in the art and the step of attaching such a material to the stent of Gray would have been obvious to one skilled in the art as it is sometimes desirable to completely isolate a portion of the body passageway from blood passing through it or increase the biocompatibility of a stent through a graft covering.

12. Regarding claims 129 and 153, Gray discloses that the ends of the stent may be thickened. If a first arcuate member in the middle of the stent is considered, it will have a greater flexibility than a thicker second arcuate member at the end of the stent (see also 35 USC 112 2<sup>nd</sup> par. rejections above).

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13. Regarding claim 144, as discussed above, the device may be shape memory and can be stable in the collapsed configuration at a first cooler temperature and stable in the expanded configuration at body temperature (col. 5 ll. 9-10 and 16-19). No stable configurations will exist between these two configurations using the two temperatures.

14. **Claim 140** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Wiktor (US 4,886,062). Gray discloses the invention substantially as stated above but does not expressly disclose locating multiple stents in the passageway such the ends of adjacent stents overlap forming a continuation of the liner element against the inner diameter of the passageway. However, Wiktor teaches that it is well known to employ multiple stents in tandem and further discloses that a balloon and stent assembly can be fed through a previously implanted stent so that a second stent may be implanted downstream of the first stent (col. 5 ll. 3-9). It would have been obvious to one skilled in the art to have modified the method of Gray to include implanting several stents within the passageway as taught by Wiktor in order to treat a larger area of a vessel. Regarding the overlapping ends, such a modification would have been obvious in order to ensure that no portion of the vessel is untreated between the stents.

#### ***Allowable Subject Matter***

15. Claims 113-118, 130-133, 135, 138, 139, 141, 145-149, 152, and 154 are allowed.

#### ***Response to Arguments***

16. Applicant's arguments filed 5/26/2009 with respect to claims 119 and 122 have been fully considered but they are not persuasive.

17. Regarding the rejection of claim 119 over Gray, applicant argues that the amendment of being capable of isothermally expanding distinguishes the instant invention from the device of

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Gray. However, the stent of Gray may be balloon expandable and therefore is capable of isothermally expanding to a stable expanded configuration.

18. Regarding claim 122, applicant argues that Gray teaches that the wave-like portions become straighter after expansion and are therefore no longer wave-like portions. This is not found persuasive since the wave-like portions are still wave-shaped after expansion as shown in fig. 3b. This may be considered straighter than before expansion (fig. 3a) but is still wave-like. In fact, the wave-like portions of Gray resemble the wave-like portions of the instant invention after expansion as shown in fig. 9 of the instant application.

19. Applicant's arguments with respect to claim 130 and its dependent claims have been considered and are persuasive. The rejections of claims 130-133, 138, 145, 146, 148, and 149 over Gray in view of Lock et al. (US 5,383,926) have been withdrawn.

20. Applicant's arguments with respect to claim 91 and its dependent claims have been considered but are moot in view of the new rejections necessitate by the amendments to the claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 9/16/2009

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
9/17/09